# GOODSENSE SPF 50 SUNSCREEN- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion Geiss, Destin, & Dunn, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# **GoodSense SPF 50 Sunscreen Lotion**

#### **Active Ingredients**

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

#### Purpose

Sunscreen

#### Uses

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

#### Warnings

#### For external use only.

**Do not use** on damaged or broken skin. **When using this product** keep out of eyes. Rinse eyes with water to remove.

#### Stop use and ask a doctor if rash occurs.

# Keep Out of Reach of Children.

If swallowed, get medical help or contact a Poison Control Center right away.

# Directions

Apply liberally 15 minutes before sun exposure. Reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

**Sun protection measures:** spending time n the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:

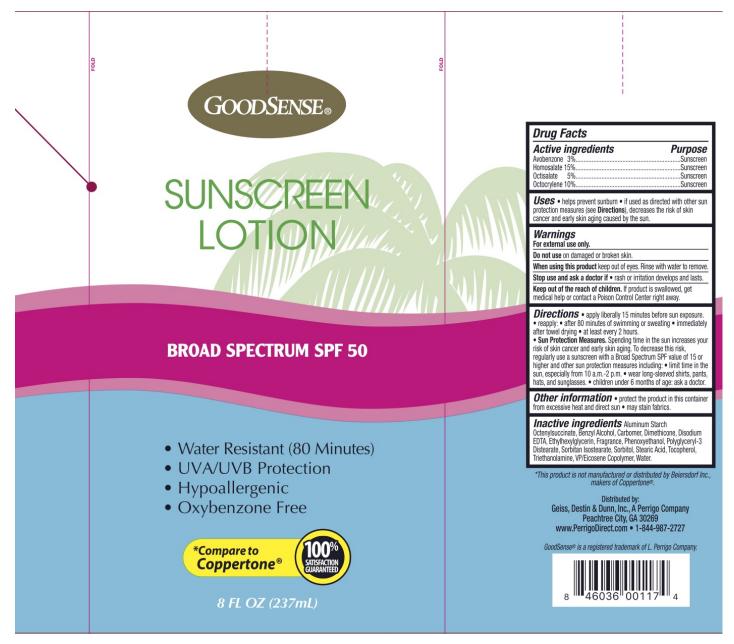
• limit time in the sun, especially from 10 am to 2 pm

- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

### **Inactive Ingredients**

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Phenoxyethanol, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

#### Label



# **GOODSENSE SPF 50 SUNSCREEN**

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion

| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)AVOBENZONE3 g in 100 mLOCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)OCTOCRYLENE10 g in 100 mL   | Ρ            | roduct Info                     | rmation                           |                                    |           |                |        |               |  |  |
|--|--------------|---------------------------------|-----------------------------------|------------------------------------|-----------|----------------|--------|---------------|--|--|
| Active Ingredient/Active Moiety         Ingredient Name       Basis of Strength       Strength         OCTISALATE (UNII: 4X49Y0596W) OCTISALATE (UNII: 4X49Y0596W)       OCTISALATE 5 g in 100 mL         AVOBENZONE (UNII: 663Q0F2NOX) (AVOBENZONE - UNII: 5663Q0F2NOX)       AVOBENZONE (UNII: SA68WGF6WM) OCTOCRYLENE (UNII: SA68WGF6WM)         OCTOCRYLENE (UNII: SA68WGF6WM) OCTOCRYLENE - UNII: 5668VGF6WM)       OCTOCRYLENE (UNII: SA68WGF6WM) OCTOCRYLENE ID g in 100 mL         Inactive Ingredients         Ingredient Name       Strength         Ingredient Name       Strength         Ingredient Name       Strength         Ingredient Name       Strength         TROLAMINE (UNII: 903K9353TK)       EDETATE DISODIUM (UNII: 7EL091266K)       EICOSYL POVIDONE (UNII: 7EL091266K)         EICOSYL POVIDONE (UNII: 7EL091266K)       EICOSYL POVIDONE (UNII: 802B2556P8)       EBENTL ALCOHOL (UNII: R0ZB2556P8)         BENZYL ALCOHOL (UNII: E02B2556P8)       EBENZYL ALCOHOL (UNII: E04594WMH)       EIFUTHEXYLEXYLEXYLEXYLEXYLEXYLEXYLEXYLEXYLEXYL  | Product Type |                                 |                                   | HUMAN OTC DRUG Item Cod            |           | de (Source)    | NDC    | DC:50804-083  |  |  |
| Ingredient Name         Basis of Strength         Strength           DCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)         OCTISALATE         5 g in 100 mL           AVOBENZONE (UNII: 633Q0F2NOX) (AVOBENZONE - UNII:563Q0F2NOX)         AVOBENZONE         3 g in 100 mL           DCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:563Q0F2NOX)         AVOBENZONE         3 g in 100 mL           DCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:563Q0F2NOX)         AVOBENZONE         3 g in 100 mL           DOCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:506SV4M955)         HOMOSALATE         10 g in 100 mL           Inactive Ingredients         Ingredient Name         Strength           Inactive Ingredients         Strength         Strength           Indicative Ingredients         Strength         Strength           Indicative Ingredients         Strength         Strength           Indicative Ingredients         Strength         Strength           Ingredient Name         Strength <th>Re</th> <th colspan="9">Route of Administration TOPICAL</th>   | Re           | Route of Administration TOPICAL |                                   |                                    |           |                |        |               |  |  |
| Ingredient Name         Basis of Strength         Strength           OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)         OCTISALATE         5 g in 100 mL           AVOBENZONE (UNII: 633Q0F2NOX) (AVOBENZONE - UNII:563Q0F2NOX)         AVOBENZONE         3 g in 100 mL           OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:563Q0F2NOX)         AVOBENZONE         10 g in 100 mL           DOCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5068WGF6WM)         OCTOCRYLENE         10 g in 100 mL           Inactive Ingredients         Ingredient Name         Strength           Inactive Ingredients         Strength         Strength           Indextree (UNII: 903K9353TK)         EECOSYL POVIDONE (UNII: 7FLD3IC86K)         EECOSYL POVIDONE (UNII: 7FLD3IC86K)           EECOSYL POVIDONE (UNII: 7Q09MKE28J)         AUDMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)         EECOSYL POVIDONE (UNII: R0Z B2556P8)           BENZYL ALCOHOL (UNII: EXG2494WBH)         EETHYLHEXYLGLYCERIN (UNII: 147D247K3P)         EPHENOXYETHANOL (UNII: E149223T)           POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV)         SORBITOL (UNII: 506760A2R)         STEARCH CUNII: 505760A2R)           STEARCH COL (UNII: 4LVTZ 65AP)         EXTERACTE (UNII: 015262C1E4)         SORBITOL (UNII: 4LVTZ 65AP)           WATER (UNII: 0599F0KO0R)         Z37 mL in 1 B0TTLE, PLASTIC; Type 0: Not a         06/12/2020           Marketing Information         <   |              |                                 |                                   |                                    |           |                |        |               |  |  |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)     OCTISALATE     5 g in 100 mL       AVOBENZONE (UNII: 6G30QF2NOX) (AVOBENZONE - UNII:5G63QQF2NOX)     AVOBENZONE     3 g in 100 mL       OCTOCRYLENE (UNII: SA68WGF6WM) (OCTOCRYLENE - UNII:5G63QQF2NOX)     OCTOCRYLENE     10 g in 100 mL       OCTOCRYLENE (UNII: SA68WGF6WM) (OCTOCRYLENE - UNII:5G63QQF2NOX)     OCTOCRYLENE     10 g in 100 mL       Inactive Ingredients     Ingredient Name     Strength       Inactive Ingredients     Strength     Strength       Inactive UNII: 903K9353TK)     EDETATE DISODIUM (UNII: 7FLD91C86K)     Strength       ELCOSYL POVIDONE (UNII: XQQ9MKE2B))     AUUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)     Strength       TOCOPHEROL (UNII: XQQ9MKE2B))     BENZYL ALCOHOL (UNII: 102B2556P8)     Strength       BENZYL ALCOHOL (UNII: 1120247K3P)     PHENOXYETHANOL (UNII: 211K470XV)     SORBITAN ISOSTEARATE (UNII: 211K470XV)       SORBITAN ISOSTEARATE (UNII: 211K470XV)     SORBITAN ISOSTEARATE (UNII: 211K470XV)     SORBITOL (UNII: 4LV7Z65AP)       WATER (UNII: 059QF0KOOR)     STEARCACID (UNII: 4LV7Z65AP)     STEARCACID (UNII: 4LV7Z65AP)       WATER (UNII: 059QF0KOOR)     237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a 06/12/2020     06/12/2020  | A            | ctive Ingred                    | lient/Active                      | Moiety                             |           |                |        |               |  |  |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)     AVOBENZONE     3 g in 100 mL       COCTOCRYLENE (UNII: SA68WGF6WM) (OCTOCRYLENE - UNII:SA68WGF6WM)     OCTOCRYLENE     10 g in 100 mL       Inactive Ingredients     Ingredient Name     15 g in 100 mL       Inactive Ingredients     Strength       Ingredient Name     Strength       Ingredient Information     Strength       Ingredient Information     Marketing Start       Ingredient Information     Ingredient Information   |              |                                 | Ingree                            | dient Name                         |           | Basis of St    | rength | Strength      |  |  |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)       OCTOCRYLENE       10 g in 100 m         HOMOSALATE (UNII: V06S V4M95S) (HOMOSALATE - UNII:V06S V4M95S)       HOMOSALATE       15 g in 100 m         Inactive Ingredients       Ingredient Name       Strength         TROLAMINE (UNII: 903K9353TK)       EDETATE DISODIUM (UNII: 7LD91C86K)       Ingredient Name         EICOSYL POVIDONE (UNII: X0Q9MKE2B))       ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)       Ingredient Name         TOCOPHEROL (UNII: ROZ B2556P8)       EECOSYL POVIDONE (UNII: 147D247K3P)       Ingredient Name         PHENOXYETHANOL (UNII: HI492Z23T)       POLYGLYCERNI (UNII: 121LK470XV)       Ingredient Strength         SORBITOL (UNII: S067660A25R)       STEARTE (UNII: 0152G2C1E4)       Ingredient Strength         SORBITOL (UNII: 4ELV7Z 65AP)       WATER (UNII: 059QF0KOOR)       Ingredient Strength         Packaging       Ingredient Package Description       Marketing Start         Marketing Information       O6/12/2020       Ingredient Start  | 00           | CTISALATE (UNI                  | I: 4X49Y0596W)                    | OCTISALATE - UNII:4X49Y            | )596W)    | OCTISALATE     |        | 5 g in 100 mL |  |  |
| HOMOSALATE (UNII: V065V4M955) (HOMOSALATE - UNII:V065V4M955) HOMOSALATE 15 g in 100 m<br>Inactive Ingredients<br>Ingredient Name Strength<br>TROLAMINE (UNII: 903K9353TK)<br>EDETATE DISODIUM (UNII: 7FLD91C86K)<br>EDETATE DISODIUM (UNII: 7FLD91C86K)<br>ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>FOOLSGIYCERYL-3 DISTEARATE (UNII: 211LK470XV)<br>SORBITOL (UNII: 506760A25R)<br>STEARIC ACID (UNII: 506760A25R)<br>STEARIC ACID (UNII: 506760A25R)<br>STEARIC ACID (UNII: 4ELV7Z 65AP)<br>WATER (UNII: 0590F0K00R)<br>PACKAGGIN<br>TERMIC ACID (UNII: 4ELV7Z 65AP)<br>WATER (UNII: 0590F0K00R)  | A٧           | OBENZONE (UI                    | NII: G63QQF2NO                    | X) (AVOBENZONE - UNII:G6           | 3QQF2NO   | () AVOBENZONE  |        | 3 g in 100 mL |  |  |
| Inactive Ingredients Ingredient Name Strength TROLAMINE (UNII: 903K9353TK) EDETATE DISODIUM (UNII: 7FLD91C86K) EICOSYL POVIDONE (UNII: XQQ9MKE2B)) ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294) TOCOPHEROL (UMII: R0ZB2556P8) BENZYL ALCOHOL (UNII: 147D247K3P) PHENOXYETHANOL (UNII: 1147D247K3P) PHENOXYETHANOL (UNII: 1147D247K3P) PHENOXYETHANOL (UNII: 1147D247K3P) POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV) SORBITAN ISOSTEARATE (UNII: 212LK470XV) SORBITAN ISOSTEARATE (UNII: 212LK470XV) SORBITAN ISOSTEARATE (UNII: 212G2C1E4) SORBITOL (UNII: 506T60A25R) STEARIC ACID (UNII: 4ELV7Z65AP) WATER (UNII: 0590F0KOOR) PACKaging # tem Code Package Description Marketing Start Date Marketing Information Marketing Information Marketing Application Number or Monograph Marketing Start Date OTC monograph not nart352 06/12/2020   | 00           | CTOCRYLENE (U                   | JNII: 5A68WGF6V                   | M) (OCTOCRYLENE - UNII:5           | 5A68WGF6V | M) OCTOCRYLENE |        | 10 g in 100 m |  |  |
| Ingredient Name Strength TROLAMINE (UNII: 903K9353TK) EDETATE DISODIUM (UNII: 7FLD91C86K) EICOSYL POVIDONE (UNII: XQQ9MKE2BJ) ALUMINUM STARCH OCTENVLSUCCINATE (UNII: 19PJ006294) TOCOPHEROL (UNII: ROZ B2556P8) BENZYL ALCOHOL (UNII: LKG8494WBH) ETHYLHEXYLGLYCERN (UNII: LKG8494WBH) ETHYLHEXYLGLYCERN (UNII: 2112K470XV) SORBITAN ISOSTEARATE (UNII: 2112K470XV) SORBITAN ISOSTEARATE (UNII: 2112K470XV) SORBITAN ISOSTEARATE (UNII: 2112K470XV) SORBITAN ISOSTEARATE (UNII: 2112K470XV) SORBITOL (UNII: 506T60A25R) STEARIC ACID (UNII: 4ELV7Z65AP) WATER (UNII: 59QF0K00R)   PACKaging  # Item Code Package Description Marketing Start Obte Combination Product  Marketing Information  Marketing Information  Marketing Information  TC monograph not part252  DTC monograph not part252  DTC monograph not part252  DTC monograph not part252  STEARIC ACID (UNII: part252  STEARIC COMPARIANCE COMPARIAN | нс           | DMOSALATE (U                    | NII: V06SV4M95S                   | ) (HOMOSALATE - UNII:V06           | SV4M95S)  | HOMOSALATE     |        | 15 g in 100 m |  |  |
| Ingredient Name Strength TROLAMINE (UNII: 903K9353TK) EDETATE DISODIUM (UNII: 7FLD91C86K) EICOSYL POVIDONE (UNII: XQQ9MKE2BJ) ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294) TOCOPHEROL (UNII: ROZB2556P8) BENZYL ALCOHOL (UNII: LKG8494WBH) ETHYLHEXYLGLYCERNI (UNII: 14T0247K3P) PHENOXYETHANOL (UNII: 14T0247K3P) PHENOXYETHANOL (UNII: 14T0247K3P) POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV) SORBITAN ISOSTEARATE (UNII: 211LK470XV) SORBITAN ISOS |              |                                 |                                   |                                    |           |                |        |               |  |  |
| TROLAMINE (UNII: 903K93S3TK)       Image: State of the s   | In           | active Ingr                     | edients                           |                                    |           |                |        |               |  |  |
| EDETATE DISODIUM (UNII: 7FLD91C86K)<br>EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)<br>ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)<br>TOCOPHEROL (UNII: R0Z B2556P8)<br>BENZYL ALCOHOL (UNII: LKG8494WBH)<br>ETHYLHEXYLGLYCERIN (UNII: 14T0247K3P)<br>PHENOXYETHANOL (UNII: HIE492ZZ3T)<br>POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV)<br>SORBITOL (UNII: 50ST60A25R)<br>STEARIC ACID (UNII: 4ELV7Z 65AP)<br>WATER (UNII: 059QF0K00R)<br>PACKAGGING<br># Item Code Package Description Marketing Start Date<br>Date Date<br>1 NDC:50804- 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a<br>Combination Product<br>Marketing Information<br>Marketing Start Date Marketing Start Date<br>Marketing Start Date Marketing Start Date<br>Marketing Information<br>Marketing Start Date Marketing Start Date<br>06/12/2020  |              |                                 |                                   | Ingredient Name                    |           |                |        | Strength      |  |  |
| EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)<br>ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)<br>TOCOPHEROL (UNII: R0Z B2556P8)<br>BENZYL ALCOHOL (UNII: LKG8494WBH)<br>ETHYLHEXYLGLYCERIN (UNII: 1470247K3P)<br>PHENOXYETHANOL (UNII: 1470247K3P)<br>POLYGLYCERYL-3 DISTEARATE (UNII: 21LK470XV)<br>SORBITAN ISOSTEARATE (UNII: 21LK470XV)<br>SORBITAN ISOSTEARATE (UNII: 1052G2CIE4)<br>SORBITOL (UNII: 505T60A25R)<br>STEARIC ACID (UNII: 4ELV7Z 65AP)<br>WATER (UNII: 059QF0K00R)   |              | •                               | •                                 |                                    |           |                |        |               |  |  |
| ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)<br>TOCOPHEROL (UNII: R0ZB2556P8)<br>BENZYL ALCOHOL (UNII: R0ZB2556P8)<br>BENZYL ALCOHOL (UNII: R0ZB2556P8)<br>BENZYL ALCOHOL (UNII: KG8494WBH)<br>ETHYLHEXYLGLYCERIN (UNII: 1470247K3P)<br>PHENOXYETHANOL (UNII: HE492Z23T)<br>POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV)<br>SORBITAN ISOSTEARATE (UNII: 0152G2C1E4)<br>SORBITOL (UNII: 506T60A25R)<br>STEARIC ACID (UNII: 4ELV7Z65AP)<br>WATER (UNII: 059QF0K00R)<br>FACKaging<br># Item Code Package Description Marketing Start Date<br>Combination Product<br>Marketing Liformation<br>Marketing Start Dister Combination Product<br>Marketing Information<br>TC monograph not Partia Citation Number or Monograph Marketing Start Date<br>06/12/2020  |              |                                 |                                   |                                    |           |                |        |               |  |  |
| TOCOPHEROL (UNII: ROZB2556P8)<br>BENZYL ALCOHOL (UNII: LKG8494WBH)<br>ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV)<br>SORBITAN ISOSTEARATE (UNII: 0152G2C1E4)<br>SORBITOL (UNII: 506T60A25R)<br>STEARIC ACID (UNII: 4ELV7Z65AP)<br>WATER (UNII: 059QF0KOOR)   | El           | COSYL POVIDO                    | NE (UNII: XQQ91                   | /KE2BJ)                            |           |                |        |               |  |  |
| BENZYL ALCOHOL (UNII: LKG8494WBH)<br>ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>PHENOXYETHANOL (UNII: 147D247K3P)<br>POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV)<br>SORBITAN ISOSTEARATE (UNII: 0152G2C1E4)<br>SORBITOL (UNII: 506T60A25R)<br>STEARIC ACID (UNII: 4ELV7Z 65AP)<br>WATER (UNII: 059QF0K00R)<br>PACKAGGING<br># Item Code Package Description Marketing Start Marketing End<br>Date Date Date Date Date Date Date Date   | AL           | UMINUM STAR                     | CH OCTENYLSI                      | ICCINATE (UNII: 19PJ0062           | 94)       |                |        |               |  |  |
| ETHYLHEXYLGLYCERIN (UNII: 1470247K3P)<br>PHENOXYETHANOL (UNII: HIE492ZZ3T)<br>POLYGLYCERYL-3 DISTEARATE (UNII: 211LK470XV)<br>SORBITAN ISOSTEARATE (UNII: 0152G2C1E4)<br>SORBITOL (UNII: 506T60A25R)<br>STEARIC ACID (UNII: 4ELV7Z 65AP)<br>WATER (UNII: 059QF0K00R)<br>Package Description Marketing Start Date<br>1 NDC:50804-<br>083-08 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a<br>Combination Product 06/12/2020<br>Marketing Information<br>Marketing Start Date 06/12/2020  | тс           | OCOPHEROL (UI                   | NII: R0ZB2556P8                   | )                                  |           |                |        |               |  |  |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)       Image: Constraint of the second se   | BE           | NZYL ALCOHO                     | L (UNII: LKG8494                  | WBH)                               |           |                |        |               |  |  |
| PoLyGLYCERYL-3 DISTEARATE (UNII: 211LK470XV)       Image: Constraint of the state  | ET           | HYLHEXYLGLY                     | CERIN (UNII: 147                  | D247K3P)                           |           |                |        |               |  |  |
| SORBITAN ISOSTEARATE (UNII: 0152G2C1E4)         SORBITOL (UNII: 506T60A25R)         STEARIC ACID (UNII: 4ELV7Z 65AP)         WATER (UNII: 059QF0K00R)         Packaging         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50804-<br>083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       06/12/2020       06/12/2020  | PH           | IENOXYETHAN                     | <b>DL</b> (UNII: HIE492           | ZZ3T)                              |           |                |        |               |  |  |
| SORBITOL (UNII: 506T60A25R)       STEARIC ACID (UNII: 4ELV7Z65AP)         WATER (UNII: 059QF0K00R)       WATER (UNII: 059QF0K00R)         Packaging         #       Item Code       Package Description       Marketing Start Date         1       NDC:50804- 083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       06/12/2020         Marketing Information         Marketing Start Date         Marketing Start Date         Marketing Combination Product         Marketing Start Date         Marketing Start Date         Marketing Combination Product   | PC           | LYGLYCERYL-3                    | B DISTEARATE                      | UNII: ZI1LK470XV)                  |           |                |        |               |  |  |
| STEARIC ACID (UNII: 4ELV7Z 65AP)         WATER (UNII: 059QF0K00R)         Packaging         Marketing Start Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50804-<br>083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       06/12/2020       06/12/2020         Marketing End Date         Marketing Start Combination Product         Marketing Start Combination Product         Marketing Start Date         Marketing Start Date         Marketing Start Date         OFC monograph not Citation Number or Monograph Citation         OFC monograph not Date         OFC monograph not Date         OFC monograph not Date  | sc           | RBITAN ISOST                    | EARATE (UNII: 0                   | 1S2G2C1E4)                         |           |                |        |               |  |  |
| WATER (UNII: 059QF0K00R)         Packaging         Marketing Start Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50804-<br>083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       06/12/2020       06/12/2020         Marketing End Date         Marketing Start Date       Marketing End Date         OTC monograph not part352   | sc           | RBITOL (UNII: 5                 | 506T60A25R)                       |                                    |           |                |        |               |  |  |
| Warketing Start Date       Marketing Start Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:50804-<br>083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product       06/12/2020       06/12/2020         Marketing Information         Marketing Start Date       Marketing Start Date         OTC monograph not       part352       06/12/2020       06/12/2020  | ST           | EARIC ACID (UI                  | NII: 4ELV7Z65AP                   | )                                  |           |                |        |               |  |  |
| #       Item Code       Package Description       Marketing Start<br>Date       Marketing End<br>Date         1       NDC:50804-<br>083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a<br>Combination Product       06/12/2020         Marketing Information         Marketing Start Date         Marketing Category       Application Number or Monograph<br>Citation       Marketing Start<br>Date       Marketing Start<br>Date         OTC monograph not       part352       06/12/2020       06/12/2020  | W            | ATER (UNII: 059                 | QF0KO0R)                          |                                    |           |                |        |               |  |  |
| #       Item Code       Package Description       Marketing Start<br>Date       Marketing End<br>Date         1       NDC:50804-<br>083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a<br>Combination Product       06/12/2020         Marketing Information         Marketing Start Date         Marketing Category       Application Number or Monograph<br>Citation       Marketing Start<br>Date       Marketing Start<br>Date         OTC monograph not       part352       06/12/2020       06/12/2020  |              |                                 |                                   |                                    |           |                |        |               |  |  |
| # Item Code       Package Description       Date       Date         1       NDC:50804-<br>083-08       237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a<br>Combination Product       06/12/2020         Marketing Information       Marketing Start       Marketing End<br>Date         Marketing Category       Application Number or Monograph<br>Citation       Marketing Start       Marketing End<br>Date         OTC monograph not       part352       06/12/2020       06/12/2020   | Pa           | ackaging                        |                                   |                                    |           |                |        |               |  |  |
| 1       083-08       Combination Product       00/12/2020         Marketing Information       Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date         OTC monograph not       part352       06/12/2020       06/12/2020  | #            | ltem Code                       | Pa                                | ackage Description                 |           |                | art Ma |               |  |  |
| Marketing<br>CategoryApplication Number or Monograph<br>CitationMarketing Start<br>DateMarketing End<br>DateOTC monograph not<br>OTC monograph notnart35206/12/2020  | 1            |                                 | 237 mL in 1 BO<br>Combination Pro | TTLE, PLASTIC; Type 0: No<br>oduct | ta        | 06/12/2020     |        |               |  |  |
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|  |              |                                 | ot part352                        |                                    |           | 06/12/2020     |        |               |  |  |

Labeler - Geiss, Destin, & Dunn, Inc. (076059836)

Registrant - Derma Care Research Labs, LLC (116817470)

| Establishment            |         |           |                            |  |  |  |  |  |
|--------------------------|---------|-----------|----------------------------|--|--|--|--|--|
| Name                     | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |  |  |
| Derma Care Research Labs |         | 116817470 | manufacture(50804-083)     |  |  |  |  |  |

Revised: 1/2023

Geiss, Destin, & Dunn, Inc.